

**REMARKS****Status of the Claims**

Claims 1-23 are pending in the application. Claims 18-20 were withdrawn previously. Claims 1-17 and 21-23 were rejected.

Claim 1 has been amended to recite “n = 0-7” which is supported by the specification at paragraph [0054]. The amendment adds no new matter.

The Examiner has expanded the scope of the search and examination from that previously adopted, but has limited W to  $L^2-A^3$ . the reason for this is this:

While the entire genus as claimed is claimed to have the same utility, the W group is deemed to be substantial structural features essential to the utility of the invention as it is part of the core structure of the molecule and can either have one or two ring structures attached to it. Ring structures that are within the core structure of a molecule are extremely important as they control the size of the molecule in order to fit and interact with the desired receptor site or protein. Therefore the molecules in which W is not  $L^2-A^3$  have not and will not be examined in the instant application.

The Applicants respectfully traverse this improper restriction, which does not comport with the standards of *In re Harnisch*. The Examiner is drawing an artificial line between two alternatives for the group W in Formula I. Group W can be either  $L^2-A^3$  or  $X^1(A^1)(A^2)$ . Since  $A^1$ ,  $A^2$  and  $A^3$  are similarly described, these options differ in the number of rings present, but each of them requires one ring to be present.  $L^2-A^3$  permits only one ring, and lets the linker be longer, while the other alternative,  $X^1(A^1)(A^2)$ , limits the length of the linker when a second aromatic ring is present.

As stated in the MPEP, “unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility.” MPEP 803. the present claims describe a genus having a substantial structural feature in common, which is shown in Formula I. The standard does not say anything about requiring all rings in a structure to be identical; that is a standard that is being adopted and applied improperly.

The two alternatives for W show that W can vary, but the variation is peripheral to the conserved core of the structure that is shown in Formula I. This structure does not require both rings to be present on the group W: it has a substantial structure that is retained, a linker plus aromatic ring on N of a pyrrolidine ring, with the additional  $-N(R^2)-L^1-X^1(A^1)(A^2)$  group. Unity of invention is established where the compounds share a substantial structure in common and share a common utility. In this case, practically all of the structure is identical regardless of which W group is used; and the two alternatives for W also have a substantial common structural feature, a linking atom having an aromatic ring. The Examiner is in effect defining every single ring of a molecule as a 'core structure' without regard to its location or significance, and without regard to the evidence in the application, which proves that the second ring is tolerated but not required for the claimed activity. The optional second ring is thus clearly NOT part of the 'core' of the compounds; as shown by the examples, an additional aromatic ring can be present or absent on W.

The restriction relies upon an assertion by the Examiner that the second ring on W would make a different 'core structure'; that assertion is inconsistent with the evidence that the second ring is optional, since activity is present whether the second ring of W is present or not. Moreover, a standard that requires every ring of a compound to be present and identical, regardless of the size of the compound, is inconsistent with Harnisch. It does not require 'all rings' to be identical, just substantial common structure. Compounds which differ only by having W represent either  $L^2-A^3$  or  $X^1(A^1)(A^2)$  clearly have substantial common structure, since all of the remainder of the structure is common, and these two options themselves have significant common structure (a linker and aromatic ring).

The Applicants accordingly respectfully request reconsideration of the restriction between compounds that differ only by having  $W = L^2-A^3$  or  $W = X^1(A^1)(A^2)$ .

Rejection Under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 1-14, 16, and 21-23 were rejected for alleged failure to satisfy the written description requirement. According to the Examiner,

The instant specification discloses compounds that have either an alkylene linker substituted with (O) or a linker for L<sup>1</sup> that is –C(O)NH–. Meanwhile, the claim is defined to include many other functionalities, alone or mixed together, with no guidance as to how those would come about. Hence the specification does not teach a representative number of examples to cover the genus as claimed. Therefore, the definitions for L<sup>1</sup> and L<sup>2</sup> are not described adequately in the specification and the claims do not meet the written description provision of 35 U.S.C. 112, first paragraph.

The Applicants traverse this rejection. First, as is well established, written description does not require *any* examples: it enquires whether the invention is described in a way to show possession of the invention. ‘Possession’ in this standard does not, as is clear from the case law and the MPEP, relate to or require any actual reduction to practice or any working examples. This is demonstrated by, e.g., MPEP 2163 (emphasis added) (“If the application does not describe an actual reduction to practice, determine whether the invention is complete as evidenced by a reduction to drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole.”)

There is a ‘strong presumption’ that original claims satisfy the written description requirement, and the Examiner has not identified anything in this rejection that relates to amendments. MPEP 2163 (“There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) (“we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims”).”)

Second, generic chemical formulas are the normal and accepted way to show *possession* of a chemical invention and to satisfy the written description requirement. MPEP *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 (“In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus.”) (emphasis added). The Examiner has provided no reasoning to suggest that the formula in

this case is not an adequate description of the genus to allow a person of ordinary skill to recognize that the Applicants had possession of the claimed subject matter as a whole. Thus no basis for a rejection based on proper standards of written description was provided.

The structures in Claim 1 are supported by a description of the genus of compounds that is taken from and corresponds to the genus in the specification; so is the description of the features of the compound of Formula I mentioned by the Examiner. The person of ordinary skill would be able to “distinguish such a formula from others” based on the description of Formula I, and would be able to “identify many of the species that the claims encompass”. The written description for a chemical genus under *Eli Lilly*, requires no more than that; thus the genus of Formula I as set forth in Claim 1 satisfies the written description requirement of 35 USC 112 according to the standards in *Eli Lilly*. The Applicants respectfully request withdrawal of this rejection.

In addition, the Applicant is concerned about this basic question being raised after extensive examination, including *two Final Rejections and two RCEs*. This question was not based on any claim amendments made, apparently, but on the basis of limitations that were in the original claims. The Applicants are not aware of any changed legal standards for the written description requirement applicable to this situation, either. It is not understood why this rejection has been made at this extremely late stage of an already prolonged examination, since any such issues could and should have been raised long ago.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1-17 and 21-23 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite because Formula I in claim 1 recites a variable ‘n’ which was not defined in the claims.

Claim 1 has been amended to recite ‘n = 0-7’, which is supported by, e.g., paragraph [0054] of the specification as filed. Accordingly, it is believed this basis for rejection is overcome, too, and may be withdrawn.

Rejection Under 35 U.S.C. § 102

Claims 1-6 were rejected as allegedly anticipated by a compound in Desolms, WO 2002/20015 A1. The compound allegedly corresponds to a compound of Formula I wherein "...A<sup>1</sup>, A<sup>2</sup>, and A<sup>3</sup> are aromatic rings."

The Applicants traverse this rejection. In a restriction requirement mailed on 5/22/2006, the Office (through a different Examiner) separated all compounds wherein A<sup>1</sup>, A<sup>2</sup> or A<sup>3</sup> was a heteroaromatic ring from those wherein 'no additional heterocycle' was present besides the pyrrolidine ring of Formula I. In response, the claims were amended to remove the possibility that these aromatic groups could be a heteroaromatic ring or contain a heteroatom. Accordingly, the claims do not read on the cited compound in Desolms, because none of A<sup>1</sup>, A<sup>2</sup> or A<sup>3</sup> can correspond to the imidazole ring in the Desolms compound. The cited compound does not contain a group -L<sup>1</sup>-X<sup>1</sup>(A<sup>1</sup>)(A<sup>2</sup>) as required by claim 1. Moreover, since such compounds were removed pursuant to a restriction requirement, they cannot even be properly applied in an obviousness rejection. Thus the claims are patentable over the compound from Desolms.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw all outstanding rejections of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket No. 381092001600. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: August 29, 2008

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